IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 9574
Nigel R.A. BEELEY *et al.*	Art Unit: 1653
Appl. No.: 09/003,869	Examiner: Abdel MOHAMED
Filed: January 7, 1998	Atty. Docket: 18528.032
For: **Use of Exendins for the Reduction of Food Intake**	

Petition for Withdrawal from Issue under 37 C.F.R § 1.313(c)

Mail Stop 313(c)
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request that the above-captioned application ('869) be withdrawn from issue under 37 C.F.R. § 1.313(c)(2) for consideration of a request for continued examination (RCE) filed concurrently herewith.

The Sequence Listing in the '869 application contains 188 amino acid sequences. SEQ ID NO: 5 corresponds to formula III, an exendin agonist compound. As described below, a Sequence Listing was submitted to the United States Patent and Trademark Office after the filing date of the original application that set forth that the Xaa at position 39 (Xaa_{39}) of SEQ ID NO: 5 was proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine. The recitation in SEQ ID NO: 5 that Xaa_{39} is proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine was

not supported by the original specification. As such, Applicants petition for withdrawal from issue under 37 C.F.R. § 1.313(c)(2) for consideration of a request for continued examination filed concurrently herewith.

Statement of Facts

1. Application Serial No. 09/003,869 ('869) was filed January 7, 1998, claiming the benefit of U.S. Provisional Application Nos. 60/034,905 (filed January 7, 1997), 60/055,404 (filed August 8, 1997), 60/066,029 (filed November 14, 1997) and 60/065,442 (filed November 14, 1997), all of which were incorporated by reference in the '869 specification. *See, e.g.*, Specification at page 9, lines 12-23. The '869 specification included disclosure of methods of using exendins and exendin agonists for the reduction of food intake. The application disclosed numerous polypeptide sequences encoding exendins and exendin agonists, including exendin agonist compounds represented by formulae I, II and III. Formula III was disclosed in the specification as:

Xaa_1 Xaa_2 Xaa_3 Xaa_4 Xaa_5 Xaa_6 Xaa_7 Xaa_8 Xaa_9 Xaa_{10}

Xaa_{11} Xaa_{12} Xaa_{13} Xaa_{14} Xaa_{15} Xaa_{16} Xaa_{17} Ala Xaa_{19} Xaa_{20}

Xaa_{21} Xaa_{22} Xaa_{23} Xaa_{24} Xaa_{25} Xaa_{26} Xaa_{27} Xaa_{28} Z-1

The specification further disclosed that Z-1 could be present or absent and when present represents one of a series of possible amino acid sequences of varying lengths. One of the sequences disclosed for Z-1 was the amino acid sequence "Gly Xaa_{31} Ser Ser Gly Ala Xaa_{36} Xaa_{37} Xaa_{38} Xaa_{39}-Z2." Specification at page 25, line 19. The '869 specification disclosed for Formula III (SEQ ID NO: 5) that the Xaa at positions 31, 36, 37 and 38 "are independently Pro, homoproline, 3Hyp, 4Hyp, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine." Specification at page 25, lines 20-23. The specification did not include a similar description of Xaa_{39} to be proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine.

2. In the Office Action mailed March 31, 1999, the Office indicated that the application failed to comply with the requirements for applications containing nucleotide or

amino acid sequence disclosure. *See* Office Communication mailed March 31, 1999. In the same Office Action, the Office required compliance with the sequence rules, 37 CFR 1.821-1.825. *Id.* In particular, the Office required the Applicant to provide:

> "(1) an initial or substitute computer readable form (CRF) copy of the 'Sequence Listing;' (2) an initial or substitute paper copy of the 'Sequence Listing', as well as an amendment directing its entry into the specification; and (3) a statement that the content of the paper and computer readable copies are the same, and where applicable, include no new matter."

3. In response, Applicants provided a "computer readable form copy of the Sequence Listing, a paper copy of the Sequence Listing, a Statement Under 37 C.F.R. § 1.821(f), and a copy of the Notice to Comply." *See* Response to Communication dated July 30, 1999. The Sequence Listing contained 188 sequences, including SEQ ID NO: 5, which corresponds to Formula III as described above.

4. In the Office Communication mailed September 22, 1999, the Office indicated that the CRF could not be processed by the Scientific and Technical Information Center (SITC) because of errors. *See* Office Communication mailed September 22, 1999. The Office identified particular errors in SEQ ID NO: 4 and further requested the Applicants to "review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa." *Id.*

5. On January 21, 2000, Applicants filed a response that included, *inter alia*, an Amendment and Response that corrected typographical errors in the specification. Amendment and Response filed January 21, 2000 at page 2. The response also included a "[c]opy of Sequence Listing in paper copy and on ASCII formatted diskette." *Id.* The paper copy of the Sequence Listing provided that the Xaa at positions 31, 36, 37, 38 and 39 "are independently Pro, homoproline, 3Hyp, 4Hyp, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine." *See*, paper copy of Sequence Listing filed on January 21, 2000 at pages 8-9.

6. On January 23, 2002, Applicants filed a Continued Prosecution Application Request including a preliminary amendment amending the claims. *See* Continued Prosecution Application filed January 23, 2002. The Preliminary Amendment included only

amendments to the claims and indicated that the Examiner had acknowledged that certain claims were allowable and further amended other claims.

7. On April 15, 2004 the Office issued a Notice of Allowance and Fee(s) Due, indicating that claims 35-66, 73-100 and 105-112 were allowed. *See* Notice of Allowability mailed April 15, 2004. A copy of the claims as allowed is attached hereto as Appendix A.

8. On July 15, 2004, Applicants paid the issue fee. *See* Issue Transmittal Form mailed July 15, 2004.

Remarks

Based on the above facts, Applicants respectfully petition the Commissioner to withdrawal the application in the above-captioned matter from issue pursuant to 37 C.F.R. § 1.313(c)(2) for consideration of an RCE filed herewith. As described above, a sequence listing was submitted to the United States Patent and Trademark Office after the filing date of the original application that set forth that Xaa_{39} of SEQ ID NO: 5 was proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine. The recitation in SEQ ID NO: 5 that Xaa_{39} is proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine was not supported by the original specification. The RCE is filed solely to amend SEQ ID NO: 5 in the Sequence Listing.

Applicants submit concurrently herewith an RCE containing an amended paper copy and computer readable form (CRF) of the Sequence Listing to delete the recitation in SEQ ID NO: 5 that the Xaa at position 39 is proline, homoproline, 3-hydroxyproline, 4-hydroxyproline, thioproline, N-alkylglycine, N-alkylpentylglycine or N-alkylalanine. Support for the amendments can be found throughout the application and claims as originally filed. *See, e.g.*, Specification at page 23, line 24 through page 26, line 4. As

such, the amended SEQ ID NO: 5 is clearly supported in the originally filed specification and is therefore patentable.

Conclusion

In view of the arguments above, Applicants respectfully petition the Commissioner to withdraw the above-captioned application from issue under 37 C.F.R. § 1.313(c) to consider the concurrently filed RCE prior to issuance.

Respectfully submitted,

Date: October 21, 2004

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